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Senator Edward M. Kennedy,
Chairman,
U.S. Senate Subcommittee on Health
U.S. Senate
Washington, D.C.

Dear Senator Kennedy:

Since my testimony 17 June 1976 before the Subcommittee on Health concerning the Report of the President's Biomedical Research Panel and your questioning, as well as that of Senators Eagleton and Beall, I have been giving further thought to the matter. A recent letter from Senator Cranston, a member of the Subcommittee on Health, has likewise stimulated me to make additional comment on two issues raised by the Report.

One issue is the differentiation of biomedical research from the development of applications of new knowledge in health care.

The second issue is the form and place of responsibility in the Federal government for development of applications of new knowledge in health care.

Differentiation of Biomedical Research from the Development of Applications of New Knowledge in Health Care

This differentiation is important because, as the Congress recognizes, we need to take advantage of what is found through biomedical research by developing it for use in health care. That development for use does not take place automatically. It does not result from simply publishing research findings. It does not flow from the present activities of NIH. That agency, influenced by its research constituency and now buttressed by the Report of the President's Biomedical Research Panel, regards "explor(ing) applications of new knowledge that are effective in health care (as something) in addition to its basic mission." The quoted words come from the Report of the Panel; the underlining is mine. NIH has looked upon exploring applications in health care as a distraction from its primary mission, to be undertaken only enough to meet vigorous complaints and demands of Congress.

There is a difference between biomedical research and exploring its applications in health care. That difference should be clearly understood by all parties concerned as one basis for accomplishing the intent of

Congress that research findings be used to improve health care. One way to understand the difference is to examine carefully what is described in the words of the Panel:

> "The continuum from the development of new knowledge to the application of such knowledge in health care includes a number of steps:
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> 1. discovery, through research, of new knowledge and the relating of new knowledge to the existing base;
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> 2. translation of new knowledge, through applied research, into new technology and strategy for movement of discovery into health care;
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> 3. validation of new technology through clinical trials;
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> 4. determination of the safety and efficacy of new technology for widespread dissemination through demonstration projects;
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> 5. education of the professional community in proper use of the new technology and of the lay community on the nature of these developments; and
>
> 6. skillful and balanced application of the new developments to the population."

Step 1 is clearly in the realm of biomedical research. Steps 4, 5 and 6 are clearly beyond the realm of biomedical research. Steps 2 and 3 comprise the area of present ambiguity and uncertainty. The problem in that part of the "continuum" encompassed in Steps 2 and 3 is:

> to identify in the findings of research (from Step 1) the potential for improving health care;
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> to systematically explore that potential through development of technology and a strategy for applying it in health care; and
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> to validate that technology through clinical trials with a view to proceeding on to Steps, 4, 5 and 6.

It is in the above-underlined activities that American health policy has been weak. That weakness has been delaying disease control and giving rise to concern in the general public and in Congress that as a nation we are not doing all we can and should to advance health through prompt application of what we know in health care. Some progress, of course, is being made, for example, in the increasing use of clinical trials.

What is needed now is explicit recognition of the underlined activities in health policy; vigorous leadership and adequate funding of them; and decision as to whether they can be entrusted to the biomedical research community with its present orientation, or whether they should be combined with the activities encompassed in Steps 4, 5 and 6 and made part of a new thrust in disease control for the country.

Some examples from experience with disease control in recent decades may be helpful. In the testimony on 17 June 1976, reference was made to the Papanicolaou smear. Briefly, the chronology of that technic has been:

1928. First reference in the U.S. to possibility of using the technic against cervix cancer.

1943. Definitive work published, establishing the technic as useful in detecting cervix cancer.

1960. Less than one-half the women in the U.S. had received the smear even once.

1974. Only about three-fourths of the women in the U.S. had received the smear even once, and the most neglected were those who had the most cervix cancer. From 1950 to 1975 over a quarter-million American women died (unnecessarily) from cervix cancer.

At present considerable attention is being given to mammography (X-ray examination of the breast) as a means of combatting breast cancer. Briefly the chronology has been:

1930. First reference in the U.S. to possibility of using mammography against breast cancer.

1960. Definitive work published, establishing the technic as useful in detecting breast cancer.

1964. First (and still the only) significant clinical trial launched.

1973. Nation-wide demonstration project undertaken.

1976. Confusion as to whether the demonstration project adequately took into account the findings of the clinical trial with respect to age of women when benefit occurs, and the hazard of radiation.

With respect to anti-hypertensive drugs, the chronology briefly is:

1950. Anti-hypertensive drugs available.

1964. Clinical trial of anti-hypertensive drugs for hypertension launched.

1967, 1970. Above study reported to show effectiveness.

1974. Surveys indicate that 36 percent of males with hypertension did not even know that they had the condition; of all those with the condition (previously known and not known) only 22 percent of black males and 28 percent of white males were under adequate control.

In the case of measles:

1960. Measles vaccine first developed and used in number of small trials in children.

1963. Measles vaccine licensed and placed on market.

1970. 47 percent of U.S. children 1-13 years of age still unprotected.

1975. Continuing outbreaks of measles occur; for example, several hundred cases in San Francisco, more than in the preceding seven years.

Dozens of additional examples could be cited from the experience of recent years, using only situations now recognized. How many are unrecognized? The conclusion is clear. There has been a failure in American health policy to recognize that:

(1) Biomedical research alone is not sufficient to assure reasonably prompt application of findings to health care.

(2) Explicit attention is needed to the steps involved in moving from research findings to incorporation into health care, namely:

(a) Identification of the potential

(b) Systematic exploration of the potential.

(c) Validation through clinical trials; then demonstration projects; professional and public education; and skillful, balanced general application of new developments--for maximum benefit to the American people from their support of biomedical research.

The Panel did not make clear in its report this serious weakness nor propose effective means of dealing with it.

Form and Place of Responsiblity in the Federal Government for Development of Applications of New Knowledge in Health Care.

One important reason for inadequate attention to the development of applications of new knowledge in health care has been the failure to define the mission clearly and to place responsibility for it in the Federal government.

Since establishing in 1937 the National Cancer Institute, the first of the National Institutes of Health, and down to the present, Congress has nudged NIH toward "control" activities, i.e., developing the application of research findings to disease control. Success has been hardly outstanding. For example, the National Cancer Act of 1971 established a program whose goal was "To develop, through research and development efforts, the means to significantly reduce the morbidity and mortality from cancer." But whereas the National Cancer Institute called a series of conferences of national leaders in the biomedical research community as early as 1970 (before the Act was passed) to consider its implementation with respect to research, it was not until 1973 that the NCI called such a conference on and otherwise began seriously to approach the development of cancer control.

From time to time during the past quarter-century, the Public Health Service and, more recently, the Department of Health, Education, and Welfare established units for cancer control, heart disease control, chronic disease control, tuberculosis control, communicable disease control, regional medical program for heart disease, cancer and stroke, etc., outside the National Institutes of Health. None of these, however, ever developed a solid base of support in and outside of Congress even remotely comparable to NIH. Many explanations may be advanced, but the fact remains.

Apart from efforts to establish organized disease control activities in NIH and in the several programs referred to outside NIH but in Washington, it should also be noted that places outside Washington have been designated for the purpose of organizing disease control activities. Notable among these are the Center for Disease Control (C.D.C.), formerly the Communicable Disease Center, in Atlanta; and the National Institute for Occupational Safety and Health (NIOSH), in Cincinnati.

Somehow neither NIH nor PHS nor HEW has mounted the kind of sustained effort to develop the application of research findings to health care that would reasonably promptly take advantage of what the nation has developed in biomedical research.

Perhaps the reponsibility for this situation comes back to Congress. The latter body has defined policy and provided funds for biomedical research on the one hand, and for health care (Medi-Care, Medicaid and apparently soon some form of National Health Insurance) on the other.

But Congress has yet to define policy, establish responsiblity and provide funds for the critical link between the two. However generously our nation supports biomedical research and health care as separate entities, the failure to provide a bridge between them will mean continuing loss on both sides. We fail to benefit from research findings and we pay for out-moded and wasteful health care.

In my testimony 17 June 1976, I outlined several aspects of this problem as follows:

"1. Clear definition of the mission, especially differentiation from biomedical research as it has developed in this country; and emphasis on epidemiological studies and controlled field trials.

2. Establishment of a coherent staff and leadership dedicated to the mission, not bits and pieces scattered through NIH and other agencies of the Federal government.

3. Sufficient budget, including present allocations scattered through NIH and elsewhere in the Federal health agencies.

4. Development of a substantial partnership with those outside the Federal government, especially in state and local government, voluntary health agencies and many elements of the health professions.

5. Careful oversight by the Congress."

Some elaboration of these points may be useful.

The mission to be undertaken is to systematically (a) identify the potential for improving health in the findings of biomedical research; (b) explore the potential through technological development and strategic planning; (c) conduct clinical and field trials (demonstrations) of the technology; (d) educate the health professions and the general public concerning health care technology, its uses and limitations; and (e) promote a skillful and balanced application of new developments to benefit the population.

This mission should be differentiated from that of biomedical research, which is to discover new knowledge that may add to the potential for improving health. The mission should also be differentiated from that of health care, which is to deliver services that will improve health to the entire population. Obviously there will be overlap and interdigitation. Failure to recognize explicitly and provide for the critical mission that lies between biomedical research and health care, however, continues to be a fundamental weakness of U.S. national health policy.

To accomplish this mission will require establishment of a coherent staff and leadership dedicated to it. Presently, to the extent that this mission is undertaken, responsibility for it is scattered throughout (a) NIH; (b) specific disease control programs fitfully started and stopped by Congress and HEW, most recently in the Health Resources Administration (HRA); and (c) various other units of the Federal health establishment such as C.D.C. and NIOSH. It certainly appears that not much of this mission will be accomplished as long as Congress and HEW do not charge some unit of HEW with responsibility for it and commit sufficient funds to carry it out. Whether that unit should be NIH, C.D.C., HRA or some other should be determined by Congress after careful consideration of where the mission fits best on the basis of history, current constituency, present responsibilities and likely future development of each unit--with or without this mission. Making the best determination will require extensive and meticulous analysis.

Designating responsibility for the mission will be effective largely to the extent that it is clearly defined and sufficient resources appropriated to carry it out. Even a casual search will disclose hundreds of millions of dollars already appropriated more or less for this purpose but so diffused throughout the Federal health establishment that a critical mass of talent, organization and resources does not exist in one place. The mission will require hundreds of millions of dollars, not the billions now committed to biomedical research nor the tens of billions now committed to health care, but still essential to realizing the benefit from those larger present committments.

In this mission the Federal government cannot function effectively alone. Many other elements of our nation are already striving, some of them desperately and looking for Federal leadership, to develop the application of biomedical research findings in health care. Important among these elements are state and local governmental agencies, voluntary health agencies committed to control of specific diseases, and several groups of health professionals. A partnership should be established, with the Federal government taking the lead and providing some coherence and guidance.

Finally, of course, the Congress cannot deal with this matter "once and for all." Continuing oversight will be required.

I hope that these comments will be helpful in your consideration of this important topic.

Sincerely yours,

Lester Breslow, M.D., M.P.H.
Dean

LB/P36

cc: Senator Alan Cranston